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March 12, 2020

Dear Valued BD Alaris™ System Customer:

BD has pledged to keep you informed of developments during the current recall and distribution hold of the BD Alaris™ System announced in our letters to you on February 4, 2020 and February 14, 2020, respectively. We are committed to providing you with timely updates through this process, and we want to help minimize any potential disruption to patient care. We also are closely following developments related to the COVID-19 (coronavirus) situation, and we know this may impact your infusion pump needs.

We understand that while distribution is suspended you may have an immediate medical need that requires limited shipment of the BD Alaris™ System. As a result, we have established a process by which existing customers with Alaris™ System devices may request limited shipment of the BD Alaris™ System software compatible devices upon certification of medical necessity. The following situations may qualify for medical necessity:

- Increase in active beds due to 1) flu season; 2) other seasonal higher occupancy rates; or 3) emergent public health events (e.g., coronavirus);
- Expansion of existing units (e.g., additional beds to ICUs) and new hospital wards or wings where infusion system workflow compatibility and/or interoperability are essential to patient care;
- Additionally, your clinical leadership may identify other medical needs that require limited shipment of BD Alaris™ System infusion pumps.

BD Medical Affairs will review each certificate of medical necessity to verify medical need and may reach out directly to the authorized hospital agent during the review process for additional supporting information.

If your clinical leadership believes you have an immediate medical need that requires limited shipment of the BD Alaris™ System, you may request limited shipment upon certification of medical necessity. Otherwise, if you placed an order for the BD Alaris™ System prior to February 4, 2020, we will be unable to fulfill your order at this time. To initiate a request through our medical necessity process, please contact your BD Alaris™ System Account Executive.

In conjunction with the February 4, 2020 voluntary recall of the BD Alaris™ System, BD has been in discussions with the FDA about all modifications made since the last 510(k) clearance. We are committed to meet the FDA's expectations and ensure that distribution resumes after the new comprehensive 510(k) submission is cleared. We have dedicated extensive resources and committed internal experts to support the review and submission of this new 510(k) notice.

BD is committed to our core values of continuous improvement and doing what is right to fulfill our purpose of *Advancing the world of health*. We fully stand behind the safety and clinical benefits of the Alaris™ System and we are committed to continuing our service activities, remediations, technical support, and repairs. We recognize the disruption this may cause your clinical operations as the flu season and COVID-19 situation rapidly evolves, and we are committed to supporting you through this process.

Sincerely,

Connor L. Bates
Vice President General Management Infusion Systems
Medication Management Solutions